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EXAMINER

DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 09/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/839,065

Applicant(s)

YE ET AL.

Examiner

Matthew F DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04/20/01.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 35-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 and 41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/R strictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-34 and 41 are drawn to intravascular catheter, classified in class 604, subclass 523.
  - II. Claims 35-40 are drawn to method of making a catheter, classified in class 264, subclass 176.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by another and materially different process such as molding.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with David Crompton on 8/19/02 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-34, and 41. Affirmation of this election must be made by applicant in replying to this Office action. Claims 35-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 1, 2 and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Samson et al. (USPN 6090099). Samson et al. discloses a catheter comprising an elongated shaft, having a proximal end, a distal end and a distal tip, wherein the shaft includes an inner liner, a second layer disposed on the inner layer, a third layer disposed on the second layer and a fourth layer disposed on the third layer and a radiopaque marker. (Figure 2).

Wherein the liner comprises polytetrafluoroethylene. (Column 6, lines 16-22).

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Wherein the distal tip has a shapable length and the distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapable length. (Figure 1 and 2).

Wherein the distal tip can be heat set by steam. (Column 6, lines 30-31).

Wherein the third layer comprises a coil, and where the coil comprises steel, nickel or a non-ferrous metal. (Column 6 line 51 – Column 8, line 11).

Wherein the distal end of the shaft has an outside diameter that is less than the diameter of the proximal end of the shaft, and where the durometer is less at the distal end than at the proximal end. (Column 8, lines 49-67).

Wherein the second layer further comprises a second segment, and the second segment is disposed at the inner liner between the distal terminus and the distal end of the shaft. (Figure 2).

3. Claims 1, 2, 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Jang et al. (4898591). Jang et al. discloses a catheter comprising an elongated shaft, having a proximal end, a distal end and a distal tip, wherein the shaft includes an inner liner (36), a second layer disposed on the inner layer (30), a third layer disposed on the second layer (34) and a fourth layer disposed on the third layer (32). (Figure 2).

Wherein the distal tip has a shapable length and the distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapable length.

Wherein the distal tip can be heat set by steam.

Wherein the second layer, and the fourth layer comprises polyether block amide.

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Wherein the third layer comprises a coil, and where the coil comprises steel, nickel or a non-ferrous metal.

Wherein the distal end of the shaft has an outside diameter that is less than the diameter of the proximal end of the shaft, and where the durometer is less at the distal end than at the proximal end.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 – 6, 8 – 11, 13, 14, 15, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sampson et al. Sampson et al. discloses the claimed invention except wherein the distal terminus is about 4 millimeters from the distal end. It would have been an obvious matter of design choice to one skilled in the art to modify the apparatus as taught by Sampson et al. to have a distal terminus 4 millimeters from the distal end, since applicant has not disclosed that 4 millimeters provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any length from the distal terminus, such as the length as taught by Sampson et al. which is less than 2 centimeters as taught by Sampson et al. for the reasoning of allowing a more flexible distal end.

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6. Claims 1 – 5, 7 – 14, 17, 18 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jang et al. Jang et al. discloses the claimed invention except wherein the distal terminus is about 4 millimeters from the distal end. It would have been an obvious matter of design choice to one skilled in the art to modify the apparatus as taught by Jang et al. to have a distal terminus 4 millimeters from the distal end, since applicant has not disclosed that 4 millimeters provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any length from the distal terminus, such as the variety as taught by Jang et al. for the reasoning of allowing a more flexible distal end, depending on the medical procedure. (Column 6, lines 15-20).

7. Claims 1-34 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sampson et al. as applied to claims 1 – 6, 8 – 11, 13, 14, 15, 17, 18 above, and further in view of Nita et al. (5951539).

Sampson et al. disclosed the claimed invention as mention above, but fails to teach the use of polyether block amide for the second and fourth layers, as well as having a multiple coil section in the proximal area and wherein the fourth layer has a greater durometer in the proximal end then in the distal end.

Nita et al. discloses an intravascular catheter with an inner layer lubricious liner, a first, helically wound coil extending over at least the more distal portions of the inner liner but preferably for most of the length of the catheter, a second, helically wound coil exterior to the first coil, located at least on the more proximal portion of the assembly but preferably for most of the length of the catheter, preferably wound in a direction

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opposite to the first coil, optionally, one or more helically wound coils placed on the proximal and mid-section of the assembly, and one or more polymeric layers variously exterior to the second coil and interior to the first coil. Further polymeric layers may also be placed between the outer polymeric covering and various and the helically wound coils. The outer polymeric covering may be composed of a series of different polymeric compositions to provide suitably differing flexibilities along the length of the assembly. The helically wound coils may be bound to the assembly via the use of radio-opaque bands or coils and may be continuously wound from a single member. The distal-most portion of the catheter assembly is very flexible but highly kink resistant. Optionally, the invention includes a catheter in which only the more distal catheter section incorporates multiple coil stiffener members. (Figures 2E, 2F, 4, 7, 8, 9, and 10).

At the time of the invention it would have been obvious to one of ordinary skill in the art to combine Sampson et al. with Nita et al. because Nita et al. taught having outer polymeric tubing sections with different durometers (Column 12, lines 46-62), which allows for an increase in flexibility and maneuverability. Nita et al. also taught having a single coil in the distal end and then multiple coils in the proximal end, which allows for a greater "pushability" (Column 9, lines 9-27). Nita et al. also disclosed using polyether block amide in the polymeric layers because of the qualities the composition possess in the area of torsion modulus, flexibility and column strength.

Therefore, it would have been obvious to combine Sampson et al. with Nina et al. to obtain the invention as specified in claims 1-34 and 41.



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8. Claims 1-34 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jang et al. as applied to claims 1 – 5, 7 – 14, 17, 18 and 41 above, and further in view of Nita et al.

Jang et al. disclosed the claimed invention as mention above, but fails to teach the catheter having a multiple coil section in the proximal area and wherein the fourth layer has a greater durometer in the proximal end then in the distal end.

Nita et al. discloses an intravascular catheter with an inner layer lubricious liner, a first, helically wound coil extending over at least the more distal portions of the inner liner but preferably for most of the length of the catheter, a second, helically wound coil exterior to the first coil, located at least on the more proximal portion of the assembly but preferably for most of the length of the catheter, preferably wound in a direction opposite to the first coil, optionally, one or more helically wound coils placed on the proximal and mid-section of the assembly, and one or more polymeric layers variously exterior to the second coil and interior to the first coil. Further polymeric layers may also be placed between the outer polymeric covering and various and the helically wound coils. The outer polymeric covering may be composed of a series of different polymeric compositions to provide suitably differing flexibilities along the length of the assembly. The helically wound coils may be bound to the assembly via the use of radio-opaque bands or coils and may be continuously wound from a single member. The distal-most portion of the catheter assembly is very flexible but highly kink resistant. Optionally, the invention includes a catheter in which only the more distal catheter section incorporates multiple coil stiffener members. (Figures 2E, 2F, 4, 7, 8, 9, and 10).

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At the time of the invention it would have been obvious to one of ordinary skill in the art to combine Jang et al. with Nita et al. because Nita et al. taught having outer polymeric tubing sections with different durometers (Column 12, lines 46-62), which allows for an increase in flexibility and maneuverability. Nita et al. also taught having a single coil in the distal end and then multiple coils in the proximal end, which allows for a greater "pushability" (Column 9, lines 9-27). Nita et al. also disclosed using polyether block amide in the polymeric layers because of the qualities the composition possess in the area of torsion modulus, flexibility and column strength

Therefore, it would have been obvious to combine Jang et al. with Nina et al. to obtain the invention as specified in claims 1-34, and 41.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 8:30-6:00.

September 4, 2002



ANH TUAN T. NGUYEN  
PRIMARY EXAMINER

7/9/02